JUN 1 2 2001

510(k) Summary

510(k) Number: K011007
Contact Person: Ann Waterhouse, Regulatory Affairs Specialist
Date Prepared: April 3, 2001

Trade/Proprietary Name: Tenodesis Screw
Classification Name: Fastener, fixation, non-degradable, soft tissue
Predicate Devices: Talon Anchor Snap-Pak by Mitek Products, RC Multisuture Bone Anchor Model 4453 by Innovasive Devices, Inc., Multitak SS Buttons by Bonutti Research, KSEA Flipptack by Karl Storz Endoscopy-America, and Acumed Suture Anchor by Acumed, Inc.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Intended Use:

The Arthrex Tenodesis Screw is intended for arthroscopic and limited mini-open surgeries requiring soft tissue fixation to bone for repair of shoulder, hand/wrist, foot/ankle, knee, and elbow.

Description:

The Arthrex Tenodesis Screw is a manually operated surgical implant intended for suture fixation in the repair of tendons and ligaments. The implant is constructed of titanium and the suture is composed of #2 braided polyester. These components are used in a wide variety of cleared medical devices and implants of this type.

Substantial Equivalence:

The Arthrex, Inc. Tenodesis Screw is substantially equivalent to predicate devices where the basic features and intended uses are the same. Minor differences between the Tenodesis Screw and predicate devices do not raise any questions concerning safety and effectiveness and have no apparent effect on the performance, function, or intended use of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 2 2001

Ms. Ann Waterhouse
Regulatory Affairs Specialist
Arthrex, Inc.
2885 South Horseshoe Drive
Naples, Florida 34104

Re: K011007
Trade Name: Arthrex Tenodesis Screw, 5.5 mm
Regulation Number: 888.3040
Regulatory Class: II
Product Code: MBI
Dated: April 3, 2001
Received: April 4, 2001

Dear Ms. Waterhouse:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): **K011007**

Device Name: **Tenodesis Screw, 5.5 mm**

Indications for Use:

The Arthrex Tenodesis Screw, 5.5 mm for fixation of tissue grafts is intended for interference fixation of soft tissue grafts in the shoulder, elbow, wrist, and ankle. These surgeries will be performed by both open and arthroscopic means.

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction

Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair

*This system is to be used in association with adequate post-operative immobilization.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(Option Format 3-10-98)

510(k) Number K011007